

Message

From: Jones, Russell [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4795FDC630C34BE4AED0C6416A20D606-RUSSELL JONES]
Sent: 5/16/2019 3:35:39 PM
To: Chumble, Prasad [Chumble.Prasad@epa.gov]; Sible, Connor Nelson [sible2@illinois.edu]
CC: Below, Frederick E Jr [fbelow@illinois.edu]
Subject: RE: Plant Growth Regulator and Biostimulant Label Guidelines
Attachments: EPA-HQ-OPP-2018-0258-0002.pdf

Connor:

Thank you for your inquiry. Prasad Chumble forwarded your request for information to me as the technical contact for the draft "Plant Regulator Guidance" posted for public comment on March 25.

I understand some of the confusion that can arise in this area in regard to definitions especially when it comes to "scientific" definitions vs. "legal" definitions. Before I go any further, please understand that "legal" definitions that are found in Federal Laws, Acts, Bills, etc. as well as in the Code of Federal Regulations (the CFR) may not always make completely make sense when it comes to academic science. When it comes to a definition found in a Federal Law (e.g. Federal Insecticide, Fungicide, and Rodenticide Act, aka FIFRA) it is the end result of numerous interactions with all potential stakeholders inside and outside of government and the scientific arena. Affected industries, NGOs, innumerable lobbying groups, academics, and Federal scientists (and their politically-appointed leadership) all have input into the final product that appears in the CFR.

As an aside, a Federal Law (such as FIFRA) grants authority to a particular Agency to establish regulations. The Agency must then develop a regulatory framework to implement that law. For EPA, FIFRA authorizes EPA's Office of Pesticide Programs to regulate the use of pesticides as assess them for human health and environmental safety. The regulations found in Title 40 Parts 150 to 189 of the Code of Federal Regulations (40 CFR §150-189) are the means by which OPP implements FIFRA.

Since 1980 (when I was a Ph.D. grad student in Agronomy at the University of Arkansas) until now (20+ years in the Biopesticides Division at EPA) I have been on both sides of the science/regulatory fence described above.

Now to answer your questions more specifically:

The recent passage of the 2018 Farm Bill established a legal definition for the universe of products called Plant Biostimulants:

A "plant biostimulant" is considered a substance or micro-organism that, when applied to seeds, plants, or the rhizosphere, stimulates natural processes to enhance or benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, or crop quality and yield."

It should be understood that the Farm Bill legislation does not amend FIFRA. No definition for a Plant Biostimulant (PBS) exists in FIFRA. Since an Agency can only regulate what is defined in its part of the CFR, EPA does not regulate a product just because it is called a PBS. What EPA/OPP is authorized to regulate are pesticides. However, it must be understood that the term pesticides, as defined in FIFRA Section 2(u), includes more than products that are used to control pests.

Definition of a pesticide in FIFRA Section 2(u): The term "pesticide" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer.

Note that I highlighted the term Plant Regulator in the definition of a pesticide. In the universe of plant biostimulant products, some contain components and have intended uses that fit within the FIFRA definition of a Plant Regulator (as defined in FIFRA Section 2(v), whereas others do not.

Definition of a plant regulator in FIFRA Section 2(v): “any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof.” (note: we interpret “behavior” of a plant as its normal growth habit). There are certain exclusions from the plant regulator definition. If something is excluded from that definition, it is then excluded from regulation by the Agency. Excluded from the plant regulator definition are those products that are “Products intended to aid the growth of desirable plants” including: (1) plant nutrients, trace elements, nutritional chemicals, (2) plant inoculants, (3) soil amendments; and vitamin-hormones.

The actual definitions are not found in FIFRA but in the CFR under 40 CFR 152.6(g). They are as follows:
Plant nutrients are “products consisting of one or more macronutrients, or micronutrient trace elements necessary to normal growth of plants and in a form readily useable by plants” [40 CFR 156.6(g)(1)];

Plant inoculants are “products consisting of microorganisms to be applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system” [40 CFR 152.6(g)(2)];

Soil amendments (which would include soil additives and soil conditioners) are “products containing a substance or substances intended for the purpose of improving soil characteristics favorable for plant growth” [40 CFR 152.6(g)(3)]; and

Vitamin-hormone products are: “A product consisting of a mixture of plant hormones, plant nutrients, inoculants, or soil amendments is not a ‘plant regulator’ under section 2(v) of FIFRA, provided it meets the following criteria:

- (1) The product, in the undiluted package concentration at which it is distributed or sold, meets the criteria of §156.62 of this chapter for Toxicity Category III or IV; and
- (2) The product is not intended for use on food crop sites, and is labeled accordingly.” [40 CFR 152.6(f)(1)(2)]

Please note here that the term Nutritional Chemicals, excluded from the FIFRA definition of a plant regulator, is not defined either in FIFRA or in the 40 CFR. I do not know why the authors of FIFRA or the 40 CFR did not define this term.

There was a great deal of confusion over the last few years in both the legally regulated community as well as regulators of the pesticide laws at both the State and Federal level. The Guidance is intended to provide examples of product label claims (and their associated products) that are considered to be Plant Regulator (and therefore subject to regulation under FIFRA) and those that are excluded from regulation under FIFRA.

If you need any additional clarifications or discussions, please feel free to contact me (contact information provided below). You may also make comments to the Docket regarding the Guidance during the public comment period that extends to July 27, 2019.

Regards.

Russ J

Russell S. Jones, Ph.D., Senior Scientist, Technical contact for the Plant Regulator Guidance
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From: Chumble, Prasad

Sent: Tuesday, May 14, 2019 8:41 AM

To: Jones, Russell <Jones.Russell@epa.gov>; Sible, Connor Nelson <sible2@illinois.edu>

Cc: Below, Frederick E Jr <fbelow@illinois.edu>

Subject: FW: Plant Growth Regulator and Biostimulant Label Guidelines

Good morning Connor,

I am forwarding your email to Russell Jones, EPA's technical expert on biostimulant related issues. He will be better able to assist you with your questions.

Best,

Prasad Chumble
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From: Sible, Connor Nelson <sible2@illinois.edu>

Sent: Monday, May 13, 2019 3:51 PM

To: Chumble, Prasad <Chumble.Prasad@epa.gov>

Cc: Below, Frederick E Jr <fbelow@illinois.edu>

Subject: Plant Growth Regulator and Biostimulant Label Guidelines

Hello Mr. Chumble,

My name is Connor Sible and I am a graduate student at the University of Illinois under the advisement of Dr. Frederick E. Below. I am enrolled in our Crop Sciences department, and my research focus is the use of biostimulants, plant growth regulators, and biologicals for use in corn and soybean production systems.

I was reaching out to you for advice on how to best approach the classification of these products, in response to the public comment for "Guidance for Plant Regulator Label Claims, Including Plant Biostimulants." It appears that the search for a clear definition of biostimulants is still in process, and as I work and define these products in my own research, I want to best follow the same steps and guidelines being utilized by the US EPA. If you had any advice, or know who I should get in contact with regarding current biostimulant definitions and registration process your help would be greatly appreciated.

Much of my work involves field studies of these products for use to increase yields via product interactions with soils and plants through nutrient cycling, microbial interaction, drought tolerance, and general plant growth processes. The primary focus of my research is placing these products into the crop production scenarios that optimize product efficacy. Along with researching these products in field systems, I am working to differentiate the different types of products. How do biostimulants differ from PGRs, which differ from

biologicals. There are many definitions for each of those categories, in which the latest Farm Bill mentions biostimulants specifically.

I have been working to put together a classification of these products based both on active ingredients and their targeted use. As a part of this, I have started to look into the registration process for these products and there appears to be some grey areas as to the use of these products a biostimulants vs fertilizers or fertilizer additives. Any help or advice you could provide regarding my research approach towards defining these products would be greatly appreciated.

Thank you very much for your time and consideration,

Connor

Connor Sible

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